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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,195	03/07/2000	Jun-ichi Nezu	06501-057001	9418

26161 7590 07/10/2003

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 07/10/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/521,195

Applicant(s)
Ibaraki et al.

Examiner
Prema Mertz

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1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 25, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 27, and 29-49 is/are pending in the application.
- 4a) Of the above, claim(s) 27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5, 6, and 29 is/are allowed.
- 6) ☒ Claim(s) 1, 4, 7, and 30-34 is/are rejected.
- 7) ☒ Claim(s) 2-4 and 35-49 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

1. Claims 8-26, 28 have been canceled previously. Claims 1-7, 29, amended claims 30, 32, 33-34, and new claims 35-49 (Paper No. 24, 6/25/03), are under consideration.
2. Receipt of applicant's arguments and amendments filed in Paper No. 24 (6/25/03) is acknowledged.
3. The following previous rejections and objections are withdrawn in light of applicants amendments filed in Paper No. 24, 6/25/03:
 - (i) the rejection of claims 1-4, 6-7, 30-34 under 35 U.S.C. § 112, first paragraph; and
 - (ii) the rejection of claims 30, 33-34 under 35 U.S.C. § 112, second paragraph.
4. Applicant's arguments filed in Paper No. 24 (6/25/03), have been fully considered and were persuasive. The new issue is stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-Double Patenting

Non-statutory double patenting rejection (obviousness-type)

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ

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761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6a. Claims 1, 7, 30, 31, 32, 33, 34, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/798,743. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim the same polypeptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 in the instant application claims a polypeptide comprising the amino acid sequence that is at least 76% identical to SEQ ID NO:1. Claims 3, 12, 14, 28, 35-38 of U.S. Application No. 09/798,743 (having all common inventors with the instant application), claims a pharmaceutical composition of the polypeptide comprising the amino acid sequence of SEQ ID NO:1. However, SEQ ID NO:1 of U.S. Application No. 09/798,743 is 76.9% identical with SEQ ID NO:1 in the instant application. Therefore, the claims in the instant application are generic to the claims in the

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corresponding application and encompass subject matter to which the claims in 09/798,743 are a species. However, the instant claims are obvious from the claims in 09/798,743 because the claims in 09/798,743 are directed to one specific embodiment encompassed by the instant claims. The products in 09/798,743 are included in the instant claims. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that a polypeptide comprising the amino acid sequence that is at least 76% identical to SEQ ID NO:1 included the polypeptide comprising the amino acid sequence of SEQ ID NO:1 as recited in U.S. Application No. 09/798,743.

Furthermore, with respect to the "pharmaceutical composition" limitation in 09/798,743, it would have been *prima facie* obvious to one of ordinary skill in the art at the time that the invention was made, to merely admix a carrier with a known protein, and obtaining such does not render the resulting pharmaceutical composition patentable if it would have been obvious to formulate the protein with a carrier relative to its art intended use (In re Rosicky 125 USPQ 341).

The claims in 09/798,743 if infringed upon would also result in infringement of the claims of the instant application. Allowance of the pending claim, therefore, would have the effect of extending the enforceable life of the claims in 09/798,743 beyond the statutory limit.

This rejection can only be withdrawn if a terminal disclaimer is filed, so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent.

Conclusion

Claims 5,⁶29 are allowable.

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Claims 2-4, 35-49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

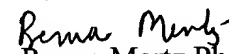
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Prema Mertz Ph.D.
Primary Examiner
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July 8, 2003